REMARKS

I. Status of Claims

Claims 1 to 22, 27 to 30, and 32 to 37 are cancelled without prejudice in response to the Restriction Requirement dated April 3, 2009. Claims 25 and 26 were previously canceled via a preliminary amendment dated March 8, 2006. Claims 31, 38, 44, 45 and 58 have been canceled in the present amendment without prejudice. Claims 23, 43, 46, 48, 50, 53, 59 and 60 have been amended. Claim 23 has been amended without prejudice to incorporate features of claims 44 and 45. Thus, support for the amendment to claim 23 can found in the specification, for example in original claim 44 and 45, as originally submitted and previously presented in the preliminary amendment dated March 8, 2006. Claims 46, 48, 50 and 53 have been amended to establish proper antecedent basis since claim 45 has been cancelled without prejudice by way of the present amendment. Claims 23, 24, 39 to 43, 46 to 57 and 59 to 64 are now pending. It is respectfully submitted that no new matter was added in this amendment.

II. Information Disclosure Statement

In the Office Action, the Examiner states that "the information disclosure statement filed May 15, 2006, fails to comply with 37 CFR 1.98(a)(1)."

In response, applicants submit herewith a Supplemental Information Disclosure Statement, along with PTO form 1449 citing the reference previously cited and submitted on May 15, 2006 and the requisite filing fee due pursuant to 37 CFR 1.17(p). Applicants believe the Supplemental Information Disclosure Statement and PTO form 1449 submitted herewith to be in compliance with 37 CFR 1.98(a)(1).

In view of the above, applicants respectfully request consideration of the information referred to in the Supplemental Information Disclosure Statement and accompanying PTO form 1449 submitted herewith.

III. Claim Rejections- 35 U.S.C. § 112

In the current Office Action, claims 23, 24, 31 and 38 to 64 were rejected under 35 U.S.C. § 112, first paragraph. Specifically, the Office Action alleges that "the specification, while being enabling for treating premature ejaculation with clomipramine, does not reasonably

provide enablement for treatment with all antidepressants." See Office Action, page 3, lines 23 to 24 through page 4, line1. In response, to expedite the prosecution of this application, independent claim 23 has been amended without prejudice in relevant part to recite "wherein the anti-depressant is clomipramine."

Claims 31, 38, 44, 45 and 58 have been canceled in the present amendment without prejudice, therefore the rejection to the aforementioned claims is now moot. The present Response refers primarily to independent claim 23 of the present invention, however, the patentability of the dependent claims 24, 39 to 43, 46 to 57 and 59 to 64 follow at least for the reason of being dependent, either directly or indirectly, from the independent claim 23 that is patentable.

In view of the foregoing, reconsideration and withdrawal of the rejection to claims 23, 24, 31 and 38 to 64under 35 U.S.C. § 112, first paragraph is respectfully requested.

In the current Office Action, claims 31, 43, 58, 59 and 60 were rejected under 35 U.S.C. § 112, second paragraph.

Claims 31 and 58 has been canceled without prejudice in the present amendment and therefore the rejection of claims 31 and 58 under 35 U.S.C. § 112, second paragraph is moot.

The Office Action states that "claims 43, 59 & 60 recite the limitation "...less than about..." which is indefinite. Claims 43, 59 and 60 have been amended in relevant part to delete the term "about".

In view of the foregoing, reconsideration and withdrawal of the rejection to claims 31, 43, 58, 59 and 60 under 35 U.S.C. § 112, second paragraph is respectfully requested.

IV. Claim Rejections- 35 U.S.C. § 102

In the current Office Action, claims 23, 24, 31, 38, 43, 44, 58, 59 and 61 to 64 were rejected under 35 U.S.C. § 102(b) as being anticipated by Tam et al. (U.S. PreGrant Publication 2002/0161016).

Independent claim 23, as amended recites: "A method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a dry powder

composition comprising an antidepressant by pulmonary inhalation, wherein the composition provides an onset of the therapeutic effect within no more than 30 minutes following pulmonary administration, and wherein the anti-depressant is clomipramine."

The Tam, et al. patent does not show or teach a method of treating premature ejaculation comprising "administering to a subject in need of such treatment a dry powder composition comprising an antidepressant by pulmonary inhalation, wherein the composition provides an onset of the therapeutic effect within no more than 30 minutes following pulmonary administration, and wherein the anti-depressant is clomipramine" as recited in amended claim 23 of the present invention.

The present Response refers primarily to independent claim 23 of the present invention, however, the patentability of the dependent claims 24, 38, 43, 44, 58, 59 and 61 to 64 follow at least for the reason of being dependent, either directly or indirectly, from the independent claim 23 that is patentable. Claims 31, 38, 44 and 58 have been cancelled without prejudice, therefore, the rejection under 35 U.S.C. § 102(b) of claims 38, 44 and 58 are moot.

In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) to claims 23, 24, 31, 38, 43, 44, 58, 59 and 61 to 64 as being anticipated by Tam et al. (U.S. PreGrant Publication 2002/0161016) is respectfully requested.

V. Claim Rejections- 35 U.S.C. § 103

In the current Office Action, claims 23, 39 to 42, 45 and 60 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tam et al. (U.S. PreGrant Publication 2002/0161016).

Independent claim 23, as amended recites: "A method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a dry powder composition comprising an antidepressant by pulmonary inhalation, wherein the composition

provides an onset of the therapeutic effect within no more than 30 minutes following pulmonary administration, and wherein the anti-depressant is clomipramine."

Tam et al. relates to compositions for the treatment of premature ejaculation. See Tam, abstract. Tam et al. concerns the formulation of solutions comprising clomipramine which may be administered by pulmonary inhalation. However, Tam et al. does not prompt a skilled person to investigate compositions for inhalation in preference to any of the other compositions disclosed in the Tam reference (such as oral. buccal or transmucosal administration of clomipramine, e.g. the tablet and gum formulations disclosed in examples 1 to 4 and 6 of Tam) and no preference is given for administration by inhalation. Moreover, no pharmacokinetic or biological data is provided in the Tam reference to reveal any advantages of one route of administration over another.

Even if a person of ordinary skill in the art would investigate inhalable compositions based on the disclosure of Tam et al., e.g. Example 3 of Tam, Applicants respectfully submit that the Tam reference does not teach dry powder compositions, and indeed the Tam reference does not disclose a dry powder composition that "provides an onset of the therapeutic effect within no more than 30 minutes following pulmonary administration" as recited in amended claim 23 of the present invention. Applicants submit herewith Appendix A providing data proving that the inhalation of the dry powder medicaments described in the present application provides a therapeutic effect to be achieved within no more than 30 minutes.

The skilled person would not have been aware of any of the advantages that the dry powder composition as described in the present application could offer over the compositions disclosed in Tam et al. (such as discussed on page 16, lines 7 to 17 of the present application - high performance pulmonary delivery of anti-depressants, enabling them to be used for reliable, convenient and efficient treatment of premature ejaculation). Therefore, the Tam reference does not show or teach "a method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a dry powder composition comprising an antidepressant by pulmonary inhalation, wherein the composition provides an onset of the therapeutic effect within no more than 30 minutes following pulmonary administration, and

wherein the anti-depressant is clomipramine" as recited in amended claim 23 of the present invention.

The present Response refers primarily to independent claim 23 of the present invention, however, the patentability of the dependent claims 39 to 42, 45 and 60 follow at least for the reason of being dependent, either directly or indirectly, from the independent claim 23 that is patentable.

In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) to claims 23, 39 to 42, 45 and 60 as being unpatentable over Tam et al. (U.S. PreGrant Publication 2002/0161016) is respectfully requested.

In the current Office Action, claims 46 to 54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tam et al. (U.S. PreGrant Publication 2002/0161016), and further in view of Staniforth et al. (U.S. PreGrant Publication 2003/0162835).

The Tam et al. reference is discussed above with respect to independent claim 23 of the present invention. Claims 46 to 54 depend, either directly or indirectly from claim 23. The patentability of dependent claims 46 to 54 follow at least for the reason of being dependent from the independent claim 23 that is patentable as discussed above.

The Staniforth et al. reference describes a method for making composite excipient particles for use in a pharmaceutical composition comprises a milling step in which particles of an excipient material are milled in the presence of an additive material; said composite particles being suitable for use in inhalable pharmaceutical compositions." See Staniforth et al., abstract.

The Staniforth et al. reference does not cure aforementioned defects of the Tam publication. Specifically, Staniforth et al. reference fails to teach "a method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a dry powder composition comprising an antidepressant by pulmonary inhalation, wherein the composition provides an onset of the therapeutic effect within no more than 30

minutes following pulmonary administration, and wherein the anti-depressant is clomipramine" as recited in amended claim 23 of the present invention. Emphasis added. Staniforth et al. does not relate to "a method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a dry powder composition comprising an antidepressant by pulmonary inhalation, wherein the composition provides an onset of the therapeutic effect within no more than 30 minutes following pulmonary administration, and wherein the anti-depressant is clomipramine" and thus cannot be readily adapted to, or readily applied to modify, the teaching of the Tam reference in order to cure the defects of the primary reference.

Therefore, the method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a dry powder composition comprising an antidepressant by pulmonary inhalation, wherein the composition provides an onset of the therapeutic effect within no more than 30 minutes following pulmonary administration, and wherein the anti-depressant is clomipramine as recited in amended claim 23 of the present invention would not have been obvious from the Tam reference, taken alone, or in combination with the Staniforth et al. reference.

As discussed above, the present Response refers primarily to independent claim 23 of the present invention, however, the patentability of the dependent claims 46 to 54 follow at least for the reason of being dependent from the independent claim 23 that is patentable.

In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) to claims 46 to 54 as being unpatentable over Tam et al. (U.S. PreGrant Publication 2002/0161016), and further in view of Staniforth et al. (U.S. PreGrant Publication 2003/0162835) is respectfully requested.

In the current Office Action, claims 55 to 57 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tam et al. (U.S. PreGrant Publication 2002/0161016), and further in view of Lewis et al. (U.S. PreGrant Publication 2002/0025299).

The Tam et al. reference is discussed above with respect to independent claim 23 of the

present invention. Claims 55 to 57 depend, either directly or indirectly from claim 23. The patentability of dependent claims 55 to 57 follow at least for the reason of being dependent from the independent claim 23 that is patentable as discussed above.

The Lewis et al. reference describes "An aerosol solution composition for use in an aerosol inhaler comprises an active material, a propellant containing a hydrofluoroalkane, a cosolvent and optionally a low volatility component to increase the mass median aerodynamic diameter (MMAD) of the aerosol particles on actuation of the inhaler." See Lewis, abstract.

The Lewis et al. reference does not cure aforementioned defects of the Tam publication. Specifically, Lewis et al. reference fails to teach "a method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a dry powder composition comprising an antidepressant by pulmonary inhalation, wherein the composition provides an onset of the therapeutic effect within no more than 30 minutes following pulmonary administration, and wherein the anti-depressant is clomipramine" as recited in amended claim 23 of the present invention. Emphasis added. Lewis et al. does not relate to "a method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a dry powder composition comprising an antidepressant by pulmonary inhalation, wherein the composition provides an onset of the therapeutic effect within no more than 30 minutes following pulmonary administration, and wherein the anti-depressant is clomipramine" and thus cannot be readily adapted to, or readily applied to modify, the teaching of the Tam reference in order to cure the defects of the primary reference.

Therefore, the method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a dry powder composition comprising an antidepressant by pulmonary inhalation, wherein the composition provides an onset of the therapeutic effect within no more than 30 minutes following pulmonary administration, and wherein the anti-depressant is clomipramine as recited in amended claim 23 of the present invention would not have been obvious from the Tam reference, taken alone, or in combination with the Lewis et al. reference

As discussed above, the present Response refers primarily to independent claim 23 of the present invention, however, the patentability of the dependent claims 55 to 57 follow at least for the reason of being dependent from the independent claim 23 that is patentable.

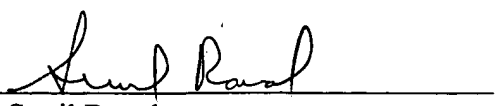
In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) to claims 55 to 57 as being unpatentable over Tam et al. (U.S. PreGrant Publication 2002/0161016), and further in view of Lewis et al. (U.S. PreGrant Publication 2002/0025299) is respectfully requested.

Conclusion

This Amendment is being submitted in response to the Office Action dated May 6, 2009 in the above-identified application. Concurrently with this Amendment, Applicant submits a petition for a one-month extension of time for filing a response, along with the requisite fee. Therefore the time for filing a response to the May 6, 2009 Office Action is thereby extended to September 6, 2009. Applicants note that September 6, 2009 is a Sunday and September 7 was a federal holiday (Labor Day), therefore the time for filing a response to the May 6, 2009 Office Action is thereby extended to September 8, 2009, and this Amendment is being timely filed. If it is determined that any additional fee is due in connection with this filing, the Commissioner is authorized to charge said fees to Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly requested.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
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APPENDIX A

European Patent Application No. 04768481.6-2114
Pharmaceutical Compositions for Treating Premature Ejaculation
Vectura Limited
Our ref: SVH/TH/46127EP1

Phase IIa proof-of-concept clinical study for VR776 (clomipramine) for the treatment of premature ejaculation

Study details

Forty patients with premature ejaculation took part in the double-blind crossover study evaluating two doses of VR776 (1 mg & 2 mg) and placebo. Following a 21 days "no treatment" run-in period, patients were randomly assigned to receive either placebo or one of the doses of VR776.

The study involved two consecutive clinical time periods (Period 1 or Period 2), wherein if the patient received drug in the first clinical time period they would not receive drug in the subsequent clinical time period and vice versa. Neither the investigator nor the patient was aware of the contents of each dose.

VR776 was delivered by oral inhalation using Vectura's Aspirair® dry powder inhaler.

Results

The pharmacokinetic data are provided below.

Subject	Period	Dose (mg)	Cmax (ng/mL)	Tmax (min)	AUC0-30 (ng/mL.min)	AUC0-t (ng/mL.min)	% AUC reached in 30 min
CT0305	1	1	18.6	1	87.2	230	37.9
CT0321	2	1	7.56	2	51.5	172	29.9
CT0333	2	1	5.99	1	67.5	243	27.8
CT0334	2	1	5.73	1	45.3	190	23.8
CT0343	1	1	30.6	1	88.9	224	39.7
CT0348	1	1	5.35	1	55	162	34.0
CT0358	2	1	9.89	1	56.1	161	34.8
CT0361	2	1	6.89	1	49.6	166	29.9
CT0364	1	1	1.35	2	10.9	18.3	59.6
CT0365	1	1	6.7	1	42.9	217	19.8
CT0366	1	1	15.5	2	108	214	50.5
CT0370	2	1	10.2	1	57.4	173	33.2
CT0376	2	1	19.1	2	103	361	28.5
CT0378	1	1	0.832	2	14.1	97.9	14.4
CT0382	2	1	37.9	3	224	410	54.6
CT0389	1	1	11.1	1	63.1	210	30.0
CT0393	1	1	8.26	1	56	166	33.7
CT0400	2	1	0.763	10	19.2	114	16.8
CT0401	2	1	1.49	1	20.8	88.7	23.4
CT0410	1	1	19.8	1	93.2	249	37.4
			11.2 ± 9.6	**1.8 ± 2.0**	**65.7 ± 45.6**	**193.3 ± 85.3**	

Subject	Period	Dose (mg)	Cmax (ng/mL)	Tmax (min)	AUC0-30 (ng/mL.min)	AUC0-t (ng/mL.min)	% AUC reached in 30 min
CT0311	2	2	6.02	2	113	428	26.4
CT0312	1	2	2.98	3	54.4	390	13.9
CT0320	2	2	34.1	3	284	694	40.9
CT0330	2	2	28	1	133	396	33.6
CT0336	1	2	11.7	1	84.5	287	29.4
CT0342	1	2	23.4	1	141	534	26.4
CT0347	1	2	6.05	1	62.3	292	21.3
CT0349	1	2	29.8	2	193	504	38.3
CT0352	2	2	13	2	79.9	345	23.2
CT0357	2	2	15	3	162	451	35.9
CT0363	1	2	3.78	1	62.7	262	23.9
CT0369	1	2	9.5	1	55.3	210	26.3
CT0371	1	2	19.9	2	198	529	37.4
CT0374	2	2	7.95	2	85.3	366	23.3
CT0381	2	2	9.17	2	108	279	38.7
CT0383	1	2	5.77	2	66.5	274	24.3
CT0386	2	2	20.4	1	153	436	35.1
CT0388	2	2	4.22	5	105	398	26.4
CT0426	1	2	18.6	1	95.3	419	22.7
CT0443	2	2	13.1	1	75.4	233	32.4
			14.1 ± 9.1	**1.9 ± 1.0**	**115.6 ± 57.6**	**386.4 ± 117.4**	

The pharmacokinetic profile demonstrates rapid onset and rapid clearance of the drug. A pharmacokinetic effect (Tmax) was achieved as quickly as one minute after dosing, while residual clomipramine levels were present within the system at 30 minutes after dosing.

The pharmacodynamic data demonstrate that VR776 significantly improves intravaginal ejaculatory latency time (IVELT) at the 2 mg dose. A clinical effect was achieved within 15 minutes of dosing; some patients reported pharmacodynamic effects as quickly as one minute after dosing. The sense of control over ejaculation felt by the patient was significantly improved. A press release verifying the pharmacodynamic data is enclosed.

Vectura announces clinical proof of concept for VR776

23 May 2007

Vectura announces clinical proof of concept for inhaled premature ejaculation product

Chippenham, UK - 23 May, 2007: Vectura Group plc (LSE: VEC) ("Vectura"), the pulmonary product development Company focused on respiratory and neurological diseases, today announces the successful outcome of a Phase IIa proof-of-concept clinical study for its product VR776 for the treatment of Premature Ejaculation (PE). The data demonstrate that VR776 improves intravaginal ejaculatory latency time (IVELT).

VR776 is Vectura's proprietary formulation of a centrally-acting drug delivered by oral inhalation using the Company's Aspirair(R) dry powder inhaler (DPI). The active component has been approved worldwide for treatment of other indications but has never been licensed for PE. Currently no product is approved in either the US or Europe for PE and a therapy with rapid onset of action could provide significant benefit for patients.

PE is defined as persistent or recurrent ejaculation sooner than desired either before or shortly after penetration, typically reflecting an IVELT of two minutes or less, over which the sufferer has minimal or no control.

Forty patients with PE took part in the double-blind crossover study evaluating two doses of VR776 (1mg & 2mg) and placebo. Following a 21 days "no treatment" run-in period, patients were randomly assigned to receive either placebo or one of the doses of VR776.

The results demonstrate:

- Statistically significant improvement of IVELT at the 2mg dose
- Clinical effect achieved within 15 minutes of dosing
- A minimal/no effect dose was established at 1mg
- The sense of control over ejaculation felt by the patient was significantly improved
- Further endorsement of patient acceptability of the Aspirair(R) inhaler

VR776 was associated with side effects of a mild-to-moderate nature, the most notable of which was incidence of cough. There were no serious adverse events and all forty patients completed the study.

Whilst the data demonstrate statistically significant changes in IVELT, Vectura believes the next stage in the development of VR776 is to establish whether bigger improvements in IVELT can be achieved at higher doses to optimise the potential therapeutic benefit. This may require re-formulation of the product in an attempt to reduce or eliminate associated cough. In line with the Company's stated strategy to focus on the development of pulmonary products for the treatment of respiratory and neurological diseases it is Vectura's intention to out-license this product.

Dr Chris Blackwell, Chief Executive of Vectura, commented:

"Premature ejaculation is a common and distinct medical condition that can severely impact quality of life, affecting the physical and emotional well-being of patients and their partners. The initial evaluation of the results of this study endorses our belief that the potential remains for VR776 to be a rapidly-acting and effective treatment for PE patients. We are also very pleased that the study

provides further validation of the effectiveness of our Aspirair(R) dry powder inhaler device."

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Notes for Editors:

About premature ejaculation
PE is the inability to delay ejaculation long enough to have a satisfactory sexual experience. It is the most common form of sexual dysfunction in men, affecting nearly 30 per cent at some time in their lives. Most often, it is due to nervousness or anxiety. PE is currently treated by counselling and/or the use of desensitising products. Recent studies have shown that centrally-acting oral anti-depressants can be effective, but the onset of action is slow. In spite of this, some are known to be used "off label" for the treatment of PE. Around 50 million males over the age of 40 are estimated to be affected by PE in the US and EU. Vectura believes that the lack of a licensed drug that specifically addresses PE, the high incidence of PE and the increasing willingness of patients to present with this problem will mean that this is an important future market for effective pharmaceutical products.

About Vectura
Vectura is a pulmonary drug development company focused principally on the development of a range of inhaled therapies for the treatment of respiratory and neurological diseases. The Company targets opportunities where optimised delivery via the lungs can provide significant benefits, such as a rapid onset of action, improved efficacy and improved tolerability compared with current therapies.

Vectura has eight marketed products and a portfolio of drugs in clinical and pre-clinical development, some of which have been licensed to major pharmaceutical companies. The Company also seeks to develop certain programmes further through development to optimise value at a later licensing stage. Vectura also offers its formulation and inhalation capabilities to other pharmaceutical companies on a licensing basis where this complements Vectura's business strategy.

Vectura has development collaborations with a broad range of pharmaceutical companies including Boehringer Ingelheim, Novartis, GSK and Chiesi. The acquisition of Innovata in January 2007 brought established alliances with a number of additional companies, such as Baxter, Merck KGaA, UCB and Otsuka as well providing revenue streams, complementary products and critical mass.

For further information, please visit Vectura's website at www.vectura.com

About Aspirair(R)
Aspirair(R) is Vectura's high performance, patent-protected single unit dose dry power inhaler, designed to allow delivery with high lung penetration and low variability, essential for drugs that are intended for systemic delivery. Vectura believes that the device is conveniently sized and simple to use compared to other 'active' inhalers. Experiments to date indicate that Aspirair (R) is capable of delivering DPI formulations of both large and small molecules, either in the form of a pure drug particle or in combination with an excipient. In laboratory tests, Aspirair(R) has been shown to consistently deliver both fine and ultra-fine particles to the deep lung regions. Aspirair(R) generates an aerosol plume, triggered by a patient's inhalation, which is significantly slower than most spray type active inhalers currently available. Thus the amount of powder that is unintentionally deposited in the mouth and throat is reduced. Aspirair(R) is currently manufactured in pilot-scale quantities

under GMP conditions by CTP Plasro, while blister filling takes place at Vectura's own GMP facility in Chippenham. Aspirair(R) has been used in patient studies in clinic and at-home settings by more than 600 subjects.

This press release contains "forward-looking statements," including statements about the discovery, development and commercialisation of products. Various risks may cause Vectura's actual results to differ materially from those expressed or implied by the forward-looking statements, including adverse results in clinical development programs; failure to obtain patent protection for discoveries; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialise products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialisation activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statement. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.